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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,501	02/04/2002	Chi-Wang Liang	13132-003001	7015
26161	7590	03/11/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			SNAY, JEFFREY R	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,501

Applicant(s)

LIANG ET AL.

Examiner

Jeffrey R. Snay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Applicant is advised that should claims 2 and 8 be found allowable, claims 16 and 23, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 6, 8, 11, 12, 14-16, 19, 23, 26, 27, 30, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuoka et al.

Fukuoka et al disclose an apparatus and method for conducting chemiluminescence assays that clearly anticipate the instant claims. Referring to Figure 1 of Fukuoka et al, the prior art apparatus comprises a light detection chamber (10) in which a specimen (14) is placed for analysis. The detection chamber includes a chamber access device (12a) which is operatively covered by a shutter mechanism (18), and a photomultiplier tube (34) which is also operatively covered by a shutter

mechanism (38). In operation, the specimen is deposited into the detection chamber via the chamber access device when the access shutter is open and PMT shutter is closed (see column 11, lines 27-47). Upon contact of the specimen with detector (66a), the shutter (18) is electronically closed. The specimen is then linearly transported to the opposite end of the chamber where a second detector (66b) is contacted to electronically open the PMT shutter mechanism. By this operational structure, the apparatus of Fukuoka et al ensures that both shutters (18 and 38) cannot be simultaneously in an open position.

The apparatus of Fukuoka et al further includes a temperature control system, including a heater (26b) and temperature sensor, for maintaining constant temperature within the specimen container (see paragraph bridging columns 8 and 9).

Regarding instant claim 11, it is noted that the horizontal carrying mechanism disclosed by Fukuoka et al would have fully anticipated the presently recited "specimen drawer." Regarding instant claim 12, it is noted that the cell port (12a) disclosed by Fukuoka et al would have fully anticipated the presently recited "openable lid."

3. Claims 1, 2, 7-13, 15, 16, 20, 23-27, 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Haunold et al.

Haunold et al disclose an apparatus and method for chemiluminescence analysis that anticipates the instant claims. Specifically, the disclosed apparatus comprises a light detection chamber (23), a photomultiplier tube (18) positioned to detect light emitted from a sample, and a dual shutter mechanism that operates such

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that a chamber access opening and the PMT opening are alternately, but not simultaneously opened. See particularly column 5, lines 54-62, for description of the mechanical operation of the two shutter devices. The PMT is depicted by Haunold et al in a side-on position.

Haunold et al further disclose the provision of a temperature control device for regulating the temperature within the detection chamber (column 4). The temperature control device includes a controller by which a user would be capable of establishing the controlled temperature at a desired level.

Regarding instant claim 11, it is noted that the rotary chamber (90) would have fully anticipated the presently recited "specimen drawer." Regarding instant claim 12, it is noted that the housing opening (94) would have fully anticipated the presently recited "openable lid."

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3-5, 17, 18, 21, 22, 28, and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Fukuoka et al and Haunold et al, as modified in view of Hiramatsu et al.

The apparatus and method of either one of Fukuoka et al and Haunold et al, as described above, differ from the claimed invention in that the prior art references fail to specify the further provision of signal processing elements for transforming the PMT output to a digital processor, such as a personal computer.

However, Hiramatsu et al discloses a similar chemiluminescence apparatus and method, which further includes electronic elements for converting the PMT signal to digital signals, and transferring such signals to a personal computer for storage, display and analysis. Hiramatsu et al further teach, for such purpose, the presence of photon counters for converting the current-based PMT signals to digital signals suitable for

computer input. It would have been obvious to modify the apparatus and method of either one of Fukuoka et al and Haunold et al to similarly include the signal processing electronics of Hiramatsu et al in order to obtain the same benefits of facilitating the desired analysis of chemiluminescent emissions from a sample.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as general background information related to applicant's field of endeavor.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'J. Snay', with a long horizontal flourish extending to the right.

Jeffrey R. Snay
Primary Examiner
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jrs